The development of an Electronic Medical Record system to improve quality of care for individuals with type 1 diabetes in Rwanda: A qualitative study

Nathalie Bille, Dirk Lund Christensen, Stine Byberg, Michael Calopietro, Crispin Gishoma, Sarah Fredsted Villadsen

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Abstract

Background: Electronic Medical Record (EMR) systems have the potential to improve quality of care and clinical outcomes for individuals with chronic and complex diseases. However, studies on the development and use of EMR systems for type 1 (T1) diabetes management in sub-Saharan Africa are few.

Objective: To analyse need for improvements in the care processes that can be facilitated by an EMR system and to develop an EMR system for increasing quality of care and clinical outcomes for individuals with T1 diabetes in Rwanda.

Methods: A qualitative, co-creative and multi-disciplinary approach involving local stakeholders, guided by the framework for complex public health interventions, were applied. Participant observation and patient's personal experiences were used as case studies to understand the clinical care context. A focus group discussion and interactive workshops were conducted to define features and content of an EMR. Data were analysed using thematic analysis.

Results: The identified themes related to features requirements were; 1. Ease of use, 2. Automatic report preparing, 3. Clinical decision support tool, 4. Data validity, 5. Patient follow-up, 6. Data protection and 7. Training. The identified themes related to content requirements were: 1. Treatment regimen, 2. Mental health and 3. Socioeconomic and demographic condition. A theory of change was developed based on the defined feature and content requirements to demonstrate how these requirements could strengthen the quality of care and improve clinical outcomes for people with T1 diabetes.

Conclusions: The EMR system, including its functionalities and content, can be developed through an inclusive and co-creative process, which improved the design phase of the EMR. The development process of the EMR system is replicable but the solution needs to be customized to fit the local context.

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Background: Electronic Medical Record (EMR) systems have the potential to improve quality of care and clinical outcomes for individuals with chronic and complex diseases. However, studies on the development and use of EMR systems for type 1 (T1) diabetes management in sub-Saharan Africa are few.

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Conclusion: The EMR system, including its functionalities and content, can be developed through an inclusive and co-creative process, which improved the design phase of the EMR. The development process of the EMR system is replicable but the solution needs to be customized to the local context.

Keywords: Type 1 diabetes, Electronic Medical Record systems, Rwanda, Complex interventions, Intervention development

Introduction

Electronic Medical Record (EMR) systems are electronic platforms that contain individual health records for patients, maintained by Health Care Professionals (HCPs) and health care organizations. EMRs may include patients' medical history, diagnoses, clinical test results and treatment plans [1]. Studies from High-Income Countries (HICs) have shown that the use of EMR systems has the potential to identify and target high risk-patients, autogenerate appointments, send reminders to patients who do not show up for consultation. Moreover, other potential benefits for the use of EMR include better organization of relevant data, and provide HCPs with feedback on their care for individuals with diabetes [2-4]. These features can lead to significant improvements in care and outcomes, as supplies, adjustments of medicines and timely referral can be better ensured [3, 5]. Little evidence is available on the development, use and effects of EMR systems for life-long chronic disease management, such as type 1 diabetes (T1 diabetes), in sub-Saharan Africa is available [6]. To increase the likelihood of successful implementation, it is crucial to know existing practices and the structure of the current system in order to know what changes are needed and feasible under the local circumstances [7]. However, studies within other disease areas such as HIV have shown positive

effects on quality of care using EMR systems [8, 9]. A study from Kenya showed that the implementation of an EMR system was significantly associated with receiving antiretroviral therapy among HIV patients and having at least one CD4 test done, compared to pre-intervention using paper records [10, 11].

Health care systems, access to health care and health care seeking behaviour, differ between countries. Requirements, priorities and local constraints related to EMR systems in low- and middle income countries (LMICs) are not well understood [12]. o understand the local context for the people and the health care system involved in the intervention, social practices, needs, possibilities and potential challenges should be taken into consideration [13]. In this study, we aimed to explore the requirements and needs for improvement in the care processes. This can be facilitated by an EMR system and how these can inform the development of an EMR system for individuals with T1 diabetes in Rwanda. Therefore, the purpose of the design stage was primarily focused on; 1. Understanding the clinical care context and workflows, 2. Defining functional requirements, 3. Defining content requirements.

Methods

Study participants

The recruitment of study participants was based on a user centred design approach and therefore included people with; a. significant understanding of the T1 diabetes care pathway and delivery of care, b. deep experience of receiving T1D care, c. expert knowledge of national digital health strategies or expertise in the design and development of electronic health record platforms (see table 1). Participants were therefore selected to reflect a range of specific characteristics and experiences known to affect the experience and delivery of healthcare including gender, years of experience, practitioner role, and diverse patient socio-economic characteristics. Initially, we identified international expert stakeholders within T1 diabetes and/or EMR systems (see Box 1), and meetings were held for inspirational and insight purposes. Thereafter, we identified relevant local stakeholders and conducted the primary data collection for the EMR development (elaborated below).

Box 1

SWEET[a]: International network for paediatric diabetes centres established in 2008, striving to improve treatment outcomes using standardized documentation and objective comparison of quality indicators.

Life for a Child (LFAC)[b]**:** An NGO established in 20020, providing young people in under-resourced countries with life-saving insulin and supplies and has the vision that no child should die of diabetes.

Changing Diabetes in Children (CDIC)[c]: A public-private partnership established in 2009. The partnership provides comprehensive care for children and young people living with type 1 diabetes in low- and middle-income countries.

International Research Institute (IRT)[d]: An independent, non-profit institute established in 1958 that provides research, development, and technical services to government and commercial clients. RTI's mission is to improve the human condition by turning knowledge into practice.

World Diabetes Foundation (WDF)[e]**:** An independent foundation founded in 2002 by Novo Nordisk A/S, and today is a leading global funder of diabetes prevention and care projects in low- and middle-income countries.

a) https://www.sweet-project.org/
b) https://lifeforachild.org/
c) https://www.novonordisk.com/sustainable-business/access-and-affordability/changing-diabetes-in-children.html
d) https://www.rti.org/
e) https://www.worlddiabetesfoundation.org/

Data collection

Researchers with training in qualitative research collected data via four activities: technical requirements focus group discussions, clinical and contextual observations, patient interviews, and user design (UX) workshops. All activities were conducted in English, except from the patient interviews which was conducted in local language [Kinyarwanda] and subsequently translated to English by a project manager. The primary data collection was conducted in November 2021 (1 month), mid-February to mid-March 2022 (1 month) and June 2022 (1 month). The different study participant types across research activities are summarized in table 1.

Table 1. Study participant types in different research activities

	Focus group	**Interactive**	**Patient interview**

	discussion	workshops	
Participant type	Number (n=10)	Number (n=8)	Number (n=13)
Caregiver (nurses, endocrinologist) [a]	7	3	-
Project Manager [a]	2	2	-
T1 diabetes individuals [b]	-	-	13
IT Expert/software developer [c]	1	2	-
Policy makers [c]	-	1	-
Sex			
Female	3	1	7
Male	7	7	6

[a] Significant understanding of the T1 diabetes care pathway and delivery of care
[b] Deep experience of receiving T1D care
[c] Expert knowledge of national digital health strategies or in the design and development of electronic health record platforms

Semi-structured focus group discussion

The purpose with the semi-structured focus group discussion (FGD) was to get a shared understanding of challenges related to current data collection practices and patient monitoring, as well as the needs and requirements for a new electronic system on how to improve the follow up and care for individuals with T1 diabetes. The participants were asked to talk about what data elements and functionalities they would like to see in a new EMR system. The group discussion was chosen to allow a more informal environment where participants could inspire and supplement each other. The participants included nurses (n=7) working at the RDA, who were familiar with current practices, and are expected to use the new EMR system. In addition to this, a few other participants with different professional backgrounds (n=3) were included, to get a full understanding of the requirements for the system and contextual insights. The FGD was held after a scheduled meeting at RDA. All participants were either recruited in person at the RDA office or by phone call and attendance was voluntary. All participants gave signed informed consent prior to the interview. A semi-structured interview guide was used, the session was audio recorded, and an assistant observer was present to take notes during the 2.5 hours interview session. An overweight of nurses from RDA, representatives of both gender and with representative age range: 24-54, mean (SD): 38.9 (10.0) were recruited.

Interactive workshops

The workshops served to make room for interaction and discussions about the EMR system requirements from a multidisciplinary group of people. Participants from all three stakeholder groups (Table 1) were invited for a joint meeting. Furthermore, four physical meetings and four online sessions with the software developer of the EMR system, a paediatrician from Rwanda Military Hospital, the management team from RDA, and the primary investigator (NB) from WDF were conducted. At the workshops, the software developer presented demo-versions of the new software and the features were discussed. Minutes from all meetings were recorded by NB and distributed for approval. From meeting to meeting, changes were suggested and subsequently, the EMR system was updated.

Participant observation and patient stories

Participant observations were conducted by the primary investigator (NB) at the RDA clinic in Kigali and at two district hospitals; Nemba Hospital and Rumera-Rukoma Hospital. The observations served to better understand the context, the workflow of the HCPs and the RDA staff, current diabetes care processes and health information collection and recording. In addition to the participant observations, patient stories were also collected at the clinic visits. During the clinic visits, ten individuals with T1 diabetes were informally interviewed (between 15 and 35 minutes). In addition, 3 individuals were invited by the Project Manager at RDA to tell their stories about how it is to live with T1 diabetes in Rwanda, and what challenges they face in seeking care and managing their disease.

Analytical approach

The analysis was inspired by a reflexive thematic approach, focusing on identifying patterned meaning (themes) in datasets [14] related to features and contents. Data triangulation methodology was applied to get a more comprehensive understanding and to enhance the validity of the analyses through convergence of information from the different data sources and methodologies [15].

The research methodology was guided by the MRC framework related to complex intervention development [16, 17]. The approach was partnership driven but also used a Theory of Change (ToC) model [17, 18]. A ToC model articulates how an intervention is expected to generate outcomes [19], thus in our case, how the EMR system is expected to link to expected outcomes (see Figure 2). Features and content to be incorporated in the EMR system were identified. 'Features' encompasses all the functionalities of the system and 'content' encompasses all the information and data elements of importance to be included in the EMR system to help the monitoring and care of T1 diabetes individuals. The needs and requirements were combined with local clinical guidelines based on international standards for T1 diabetes care.

Results

Understanding the clinical care context and workflows

Since 2009, Rwanda Diabetes Association (RDA) has been the main health care provider for T1 diabetes in Rwanda, conducting continuous follow-up on children and youth with T1 diabetes for treatment and control purposes. The RDA operate according to national diagnosis and treatment guidelines. Individuals are typically diagnosed with T1 diabetes at the local health facility, the district hospital, at a private clinic or at the RDA clinic upon presentation with symptoms of T1 diabetes. Diagnostic confirmation is usually based on glycated haemoglobin (HbA1c) testing, age at diagnosis, response to insulin, presence of diabetic ketoacidosis symptoms and underweight [20-22].

The RDA has one clinic in the capital, Kigali, and works closely with the non-communicable disease clinics at the district hospitals located throughout the country. Individuals with T1 diabetes living in the Kigali region go directly to the RDA clinic. For T1 diabetes individuals living outside of Kigali, a team of diabetes nurses and educators from RDA conduct quarterly and annual visits to the district hospitals, providing treatment and care [22, 23]. The annual visit is an extensive version of the health examination done at the quarterly visits. Within approximately three weeks of the scheduled visit, individuals with T1 diabetes or their legal guardians are notified about the next appointment date, either directly by RDA via phone call, by a nurse from the district hospital or by the community health worker within the community. On the day of the appointment, T1 diabetes individuals show up in the morning at 9:00am for plenum diabetes education followed by individual examination conducted by RDA HCPs. All data are collected on paper forms, which are subsequently registered in an excel spreadsheet database. Transfer of data from paper to spreadsheet is typically done at the end of the day, when the nurses have a nightshift or when they have some time left between other tasks. The physical copies are stored in a locked cabinet at the RDA office in Kigali. The follow-up and data collection flow are summarized in Figure 1.

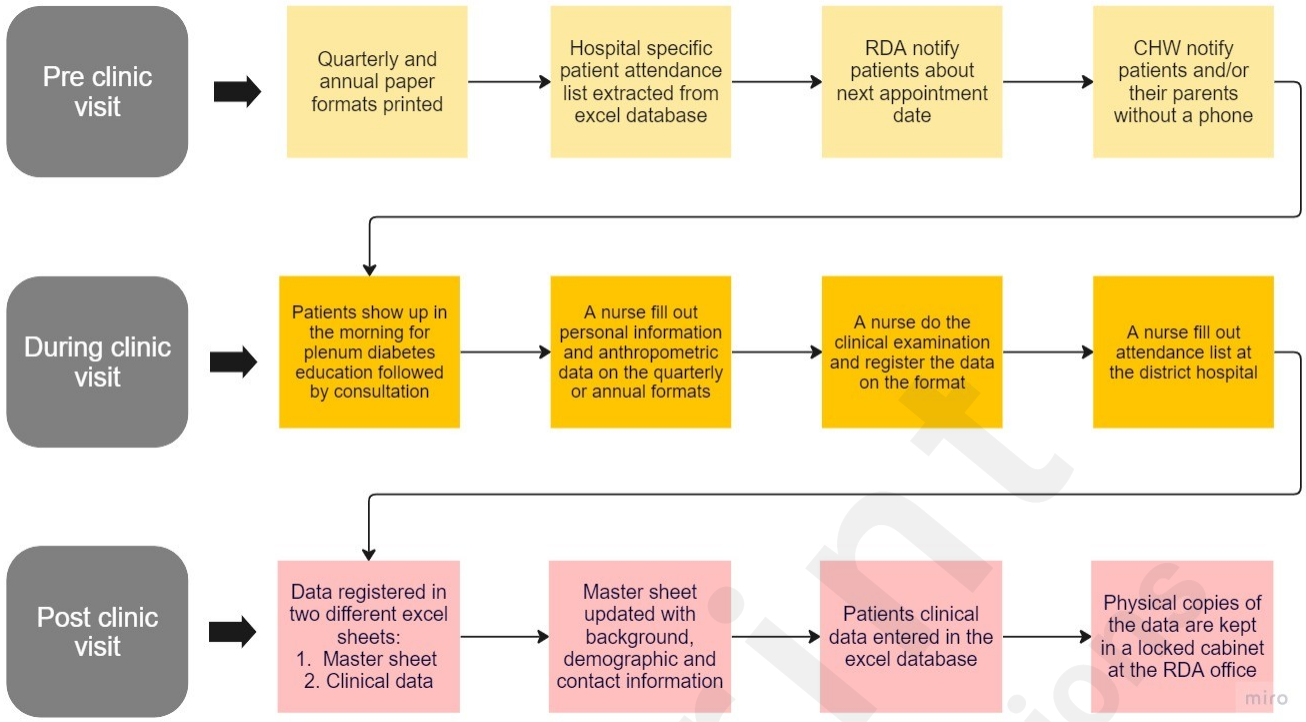

Figure 1. Follow-up and data collection flow

Feature requirement

The following themes related to the concepts of features were identified: Ease of use (user friendly), reporting (automatic report generation), Clinical decision support tool (regulation), data validity (data quality), patient follow-up, data protection and training.

Design: Ease of use - User friendly

The structure, design and interface of the system were identified as important aspects of the new EMR system. It must be user-friendly, intuitive, and developed with focus on the user (RDA staff). The HCP expressed that the structures and flows of how, and when, the different information should be obtained needed to be considered, and the data elements should be grouped in a meaningful way, as expressed by one of the project managers:

'It should be considered how we group and organise the order of the data being collected to improve efficiency. The information collected in the system should match the workflow of RDA.' **Project manager (FGD).**

Participants suggested that patient demographics are only captured one time and recorded in the registration form. Further to this, during the quarterly visit, the most important variables (vitals and results of medical tests) should be captured. Additional information related to patient characteristics that change over time (e.g. lifestyle, sociodemographic factors, mental health, etc.) and results of microvascular and macrovascular screenings. A balance between what is 'need to know' and 'nice to know' should be carefully considered taking the limited time for consultation per person into account. The less time HCPs spend on collecting and registering the data, the more time they have to do more tests, ask more questions and/or educate the individual about their disease. Therefore, fewer clicks and time optimizing functions were brought up as important factors, as one project manager explained:

'The system should have few clicks to ease the data collections processes. The system should not be too complicated to use and therefore the design and structure of the system are important.' **Project manager 1 (FGD)**

Automatic report generation

The new EMR could simplify the time-consuming task of generating frequent and routine reports. In the quote below one manager explains the tedious work of preparing the report:
'Every month RDA is obligated to upload a report with the status of the T1 diabetes individuals to the MoH. It can take 3-4 days preparing the report. It could be very helpful if the system can generate the data for the reports, including numbers of individuals with newly identified T1 diabetes.' **Project Manager 2 (workshop)**

The time gained by using web-based analysis tools for report preparation and outcome monitoring can be used for other important or patient-related tasks. The reports generated by the system should include summary statistics, including graphs and figures giving an overview of incidence and prevalence rates and the health status of the T1 diabetes population. This was expressed by one project manager:
'It will be useful if the system can provide basic statistics, so it is easier to compare patients across districts and between sex to better target actions and improve care for those who need it most… The reports can be very useful for the management team for control and target purposes.' **Project manager 1 (FGD)**

Clinician Decision support tool (regulation)

The system can generate aggregated reports, which can help track patient outcomes, support clinical management and improve clinical efficiency. The system can assist in prompt and effective patient management. At point-of-care, the RDA staff can view a summary of the medical records of the individuals with T1 diabetes, showing a chart with clinical and anthropometric measures.
'Reporting an overview of HbA1c levels, blood glucose levels, heigh, weight, BMI and diastolic and systolic blood pressure is important to see if the patients improve their glycaemic control and in other relevant factors over time.' **Project Manager 2 (workshop)**

The HCPs can track the patient's development in disease management over time as well as identify critical values using real time data. When key screening tests for comprehensive diabetes care are due or clinical test results are outside normal range the RDA staff will receive alerts to facilitate clinical decision-making and considerations for therapeutic interventions. The HCPs can change the treatment regimen according to the recorded blood glucose and HbA1c level, if values are critically high or low. Not only the system can help providing timely screening and clinical tests, but also help avoiding unnecessary examinations, saving time and resources. One nurse mentioned how care can be improved, and ultimately optimised by providing the right examination, in a timely manner:
'The system should be able to remind the HCPs when it is time for which tests, ensure timely examinations and avoid repeating exams that is not necessary. The system could also alert about critical test results to help the nurses optimizing care.' **Nurse 4 (FGD)**
Using the system and the collected data to guide the HCPs in improving the care for the individuals with T1 diabetes was a shared belief among the nurses and project managers participating in the FGD.

Data validity

Since clinical decision-making is based on the data entered and stored in the system, it is critical that the data are as reliable as possible. The EMR system should incorporate multiple functions helping the RDA staff reduce errors and limit missing information to improve the data quality. These include missing data checks, data value checks, and data logic checks. The system should help ensure that

meaningless values are avoided, expressed by a project manager:
'The system can help reduce human errors. If there are restrictions on some information, it can improve the data. The Rwandan phone numbers have 9 digits - registering more or less than 9 digits should not be allowed by the system.' **Project manager 1 (FGD)**
This does not mean that 'free text' boxes must be excluded, as not all data fit into normal and predefined categories or patterns. In the new system, some data elements require further description necessitating the inclusion of 'free text' boxes. Additionally, information boxes or subtitles should be included for specific data elements to provide clarifying information to the HCPs. For example, how a family size is defined, and the difference between prescribed and self-reported insulin dosage.

Patient follow-up

The EMR system should record scheduled visits and send SMS reminders to patients in the local language [Kinyarwanda] reminding them of the date and time of their next visit. This feature is necessary to improve clinic-visits attendance – which can be a challenge for people with T1 diabetes. If a patient does not attend a scheduled appointment, the EMR system should generate a notification so that additional action can be taken to find the patient, and to reschedule a new appointment. Tracking the number of coherent missed appointments can also help targeting efforts to find the patients. After several workshops, the clinicians agreed that lost to follow-up should be considered after three consecutive missed appointments or no-show for more than a year. This is an arbitrary definition, so it was also agreed that the threshold could be revised after an implementation evaluation. Moreover, it is important to register individuals who have passed away so that the follow-up efforts are only targeted to those still alive. The system should also track migration history easing the process of locating the right individuals. Reliable patient identification can be ensured by autogenerating unique IDs referring a numerical code to a specific patient. This feature should help supporting deduplication and avoiding two individuals having the same ID, as this confuses the identification of patients. The issue was observed from participant observations in the field:
'Sometimes when identifying people in the excel database one person was registered more than once with two different ID numbers. Also, in other occasions we found out that two different people has been given the same ID, meaning that the data was mixed.' **Participant observation**
Other relevant unique national IDs issued to citizens of Rwanda should also be stored to help identify patients and reduce duplication of patient records.

Data protection

In Rwanda, internet and electricity are available in most places throughout the country but it works with varying quality. Connectivity failure can lead to data loss if offline functioning is not in place. Therefore, the EMR system should be able to capture data offline and automatically upload it to a server or cloud-based function after re-connecting to the internet. This concern was raised by several of the nurses:
'The system cannot work without internet. Sometimes the internet fails at the countryside and in the rural areas, why it would be better if the system can work offline. The system can only be sustainable if the system works offline – offline functioning ensures that no data is lost.' **Nurse 2 (FGD)**

However, this was also discussed with a project manager and the IT expert at one of the workshops, where it was mentioned that internet connectivity rarely fails and is therefore less of a concern. It was further expressed:

'We needed to consider the pros and cons of including an offline functionality in the system because it might negatively impact the possibility of making adaption and changes in the system as we go into implementation phase.' **Software developer (workshop)**

Moreover, the patient's data should be protected and respected, and therefore the system should

comply with Rwanda's National Data Protection law [24]. Patient information should only be released and used by others with the patient's permission, giving written informed consent. The data should be secured by giving authorized access to the system with personalized usernames and passwords. Users of the system should have different authorization depending on their functions, responsibilities, and based on preestablished role-based privileges. Allowing more HCPs to have access to the data will require additional governmental approvals.

Content requirements

The following themes related to the concept of content were identified: Treatment regimen, complications, mental health and socioeconomic conditions.

Treatment regimen

The treatment regimen was mentioned as a complex matter in the care of T1 diabetes as insulin intake and treatment plans have to be individualized according to the lifestyle and general condition. The RDA staff that participated in the workshop expressed the needs that must be carefully considered providing the care:

'We experience that many patients have high blood glucose levels and we need to do something about it. The insulin dosage needs to be adjusted according to the blood sugar levels – we need to control and take actions and find the right treatment… also we need to consider the diet, physical activity and other factors that might impact the blood sugar levels.' **Project manager (workshop)**

A lot of different factors might have an influence on how the individual is managing the disease. Even though insulin is a necessity for survival it is not the only factor contributing to good diabetes management. Many individuals are still in poor control due to other factors than insulin availability and affordability. It is important to adjust and refine the insulin dosage and injections according to the time of the day, insulin type(s), food intake, physical activity level and insulin storage, as it impacts the effect if it is exposed to high temperatures. It is also crucial that the individual continuously monitors blood glucose levels if self-adjustment of insulin dosage is needed. Sometimes T1 diabetes individuals did not have access to glucometers for various reasons; the glucometer was lost, out of batteries or defected.

Complications

Information about self-reported cases of acute complications, such as diabetic ketoacidosis, hypoglycaemia and acute hospitalization, as well as information related to chronic complications should be obtained and registered in the system. This includes screening, diagnosing and referral to treatment of nephropathy (micro-albuminuria), retinopathy and neuropathy. One nurse mentioned:

'We need to screen the patients for complications to ensure timely referral and treatment... It is critical to investigate if chronic complications have developed so we can either prevent them from occur or take it into account in the care we provide.' **FGD (Nurse 4)**

Mental health

Mental health problems were mentioned to be an overlooked but serious consequence of T1 diabetes in Rwanda. Individuals are usually missed or underdiagnosed with depression. Thus, additional efforts needed to ensure a screening process for mental health issues in people living with T1 diabetes. A standardized screening tool for identifying diabetes-related distress should be incorporated in the system with the balance of being able to detect those with mental health issues, and not overloading the HCPs with too much additional work. The tool should help guide referral to a mental health specialist.

Socioeconomic conditions

Finally, socioeconomic and demographic information (e.g. educational level, job status, insurance and marital status) were considered of importance – but particularly whether or not the patient has

support from family or friends to manage the treatment regimen.

Theory of Change

The findings from the thematic analysis were used to generate a theory of change. The EMR system and its features as well as the data collected are expected to make a change. Figure 2 summarizes how the different themes identified in the analyses relate to project activities, expected output and outcomes.

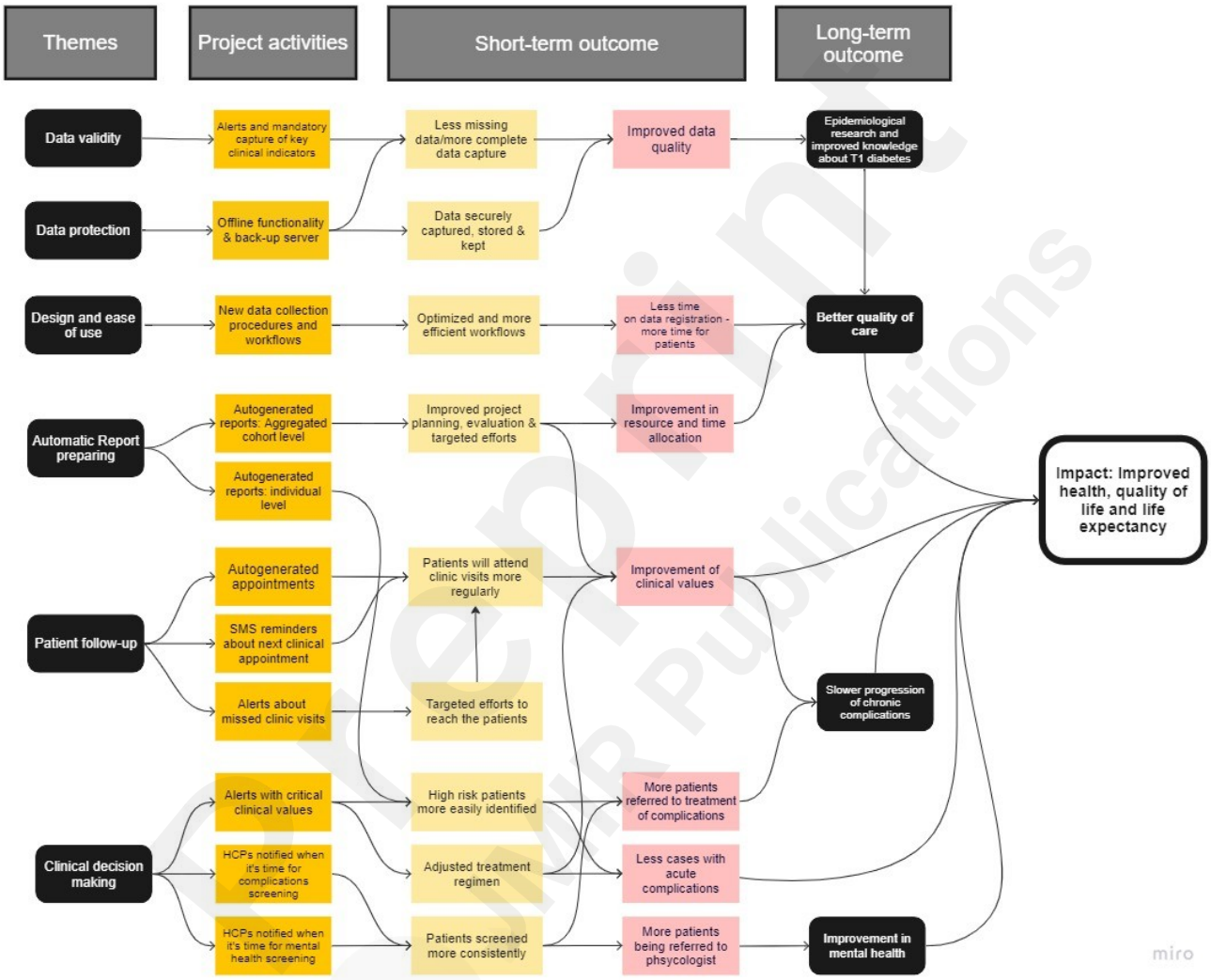

Figure 2. Theory of change – A set of assumptions about the relationship between themes, project activities and expected short and long-term outcomes.

Discussion

Summary of main findings

The features and the content of the EMR system were discussed from a perspective of improving clinical outcomes for the individuals with T1 diabetes in Rwanda. Improving clinical efficiency through a new EMR system could reduce the time spent on data registration leaving more time for consultations with T1 diabetes individuals. Automatic report generation could also reduce time and better inform HCPs and policy makers about status of the T1 diabetes care in Rwanda. This can be used to guide clinical practice, monitor clinical quality, guide service delivery planning and resource

allocation. Longitudinal data collection at the individual level should be used for tracking patients over time and support clinical decision-making. This is in addition to using real time data to guide the treatment regimen and disease management, all of which can lead to improved clinical efficiency, quality of care and better outcomes. A fundamental part of improving clinical decision-making and follow-up on individuals with T1 diabetes is the data quality to. This ensures that the right people are being timely identified and that treatment regimen are based on valid information. Moreover, it is critical to capture, store and ensure good data protection, as well as, to comply with national regulations laws to keep the data safe and confidential. It requires an offline functionality in case of internet connectivity failure and a server system to ensure back-up of the data. Finally, it is important to collect the right information (content). In addition to the clinical data, information about treatment regimen, socioeconomic condition, screening of complications and mental health status were identified as being of great importance to improve the care and clinical outcomes for the individuals with T1 diabetes.

Comparison with prior work

As research on EMR systems for T1 diabetes in LICs have been very limited, we discussed our finding with studies HICs or other disease areas. In a review by Ali et al. the enhanced functionalities integrated in the EMR systems were defined as; reminders, management prompts, self-care support, provider feedback, and patient report generation [25]. These functionalities are similar to most of the features identified of importance in this study: SMS reminders for consultation, reminders for complications screening, management prompts related to critical clinical values and missed appointments. This was in addition to better self-care support guided by data informed treatment regimen, and autogenerated reports on aggregated and individual level. Importantly, further discussions are needed on how these standardised values are interpreted in combination with the clinical decision-making. Strong clinical competences and not only technical skills are needed to navigate the EMR system without giving too much influence to the individual indicators.

We found that offline functionality was viewed as an important feature related to data protection and ensuring that data are securely captured and uploaded to a back-up server. In contrast, the benefits of using a networking EMR system were mentioned in the study by Fraser et al. [12]. It was stated that internet access allows a more flexible design, data can be more easily shared at multiple sites and multiple users can enter the data simultaneously. The study mainly included EMR systems from HICs, where internet failure is considered less of a problem. However, another study reviewing the use of EMR systems in SSA in other disease areas reported that poor network structure can be a barrier to the adaption of the EMR systems [8].

Lack of comfort among HCPs to use an EMR system has also been identified as a potential barrier, which can underscore the importance of an easy-to-use system and training of users to increase adaption to the EMR system. In the review by Fraser et al., none of the mentioned systems were designed for T1 diabetes, but aligned with the findings of this study, ease of use and training were mentioned as critical factors for a successful implementation [12]. The system should capture the minimum data necessary for the task, and data items should be structured to simplify data entry and optimise use.

In this study, treatment regimen, mental health, and sociodemographic conditions were highlighted themes of importance for good diabetes management. Khater et al., state that living with T1 diabetes, especially in LMICs, can feel overwhelming for both children and parents because of constant vigilance and complex and demanding treatment regimen are required for proper care with inadequate resources [26]. It was also found that depression in children and adolescents with T1

diabetes has been associated with sub-optimal glycaemic control and increased risk of developing complications and recurrent diabetic ketoacidosis [26]. Therefore, information related to this is critical and aligned with the findings of this study. Screening for diabetes-related distress can help refer patients to a psychologist to get better coping strategies about how to live better mentally with the disease. Moreover, having financial or demographic difficulties, e.g., living far from the hospital or having a big household might impact the patients' access to care, for example by not having enough money for transportation. Furthermore, what factors contribute exactly to good disease management and blood sugar control among Rwandan T1 diabetes individuals is still not completely clear. Therefore, all the information in the EMR system can be used to further investigate different factors which improve care and outcomes.

Limitations

This study mainly focused on the needs related to features and content and focused less on more technical aspects, such as the data model, network architecture, and software type [8, 12]. This limitation could be explained by the characteristics of the study participants primarily consisting of HCPs and individuals with T1 diabetes. Including more software developers or IT experts might have contributed to the identification of other important themes. Another overlooked topic was sustainability of the system, including budgeting, timeline, and maintenance of the system. Many IT projects fail due to lack of continued funding or a good sustainability plan. It is important to consider how the system keeps operating, what will happen in case of staff turnover, and if and/or when updates are needed in the system. It is also important to consider integration with the national health information and management system, or at least how the systems can support each other instead of operating in parallel and create double work for HCPs.

Moreover, research must occur concurrently as the pathophysiology of T1 diabetes is not fully understood. Over time, the EMR system will support data for clinical and epidemiological research. We previously investigated the association between HbA1c level and the development of nephropathy among T1 diabetes individuals in Rwanda, where it was concluded that more data are needed to know what exactly affects the blood glucose levels and the development of diabetes related complications [20].

The suggested EMR system is an early version and we cannot be sure that we have identified all relevant data elements. Interviewing more individuals living with T1 diabetes or other HCPs from other hospitals could have given other insights. It is understood that updates and revisions will be needed. Nevertheless, it's a strength of this study that triangulation between data sources and methodologies were applied to obtain a comprehensive understanding of the needs and requirements in this specific context [15]. Future research is needed to verify the ToC, analyse whether the system can be used as intended and will lead to the expected improvements in clinical outcomes, as also suggested in the MRC framework.
As shown above, many aspects of our study were in accordance with previous research from other settings. Thus, the EMR system and the development process may be replicable in other LMICs and for disease areas other than T1 diabetes, but we recommend taking caution and considering context specific customization. We are critical of the "one-size-fits-all" approach, but neither do we believe that we have to "reinvent the wheel" if someone wants to adapt an EMR system for better disease management.

Conclusion

This study concludes that themes related to 'features' and 'content' are important to identify and

consider when developing an EMR system for T1 diabetes management in Rwanda. The suggested EMR system is expected to improve data quality, optimize workflows and save more time for the patients, improving clinical values and ensure more patients are referred to treatment of complications in a timely manner. Hopefully, this will lead to slower progression of chronic complications, more research in the area to further improve and optimize care, and eventually have a long-term impact on improving health, quality of life, and reduced mortality rates among T1 diabetes individuals.

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Ethical statement

The project was approved by the Institutional Review Board, College of Medicine and Health Sciences, University of Rwanda (FWA assurance No. 0001971, IRB 00001497 of IORG 0001100).

Conflict of Interest

NB and MC are employees of WDF, DLC has received payment from Novo Nordisk Mexico for consultancy work, and CG is an employee of RDA. The remaining authors declare that they have no known personal relationships or competing financial interests, which could have influenced the work and results presented in this paper.

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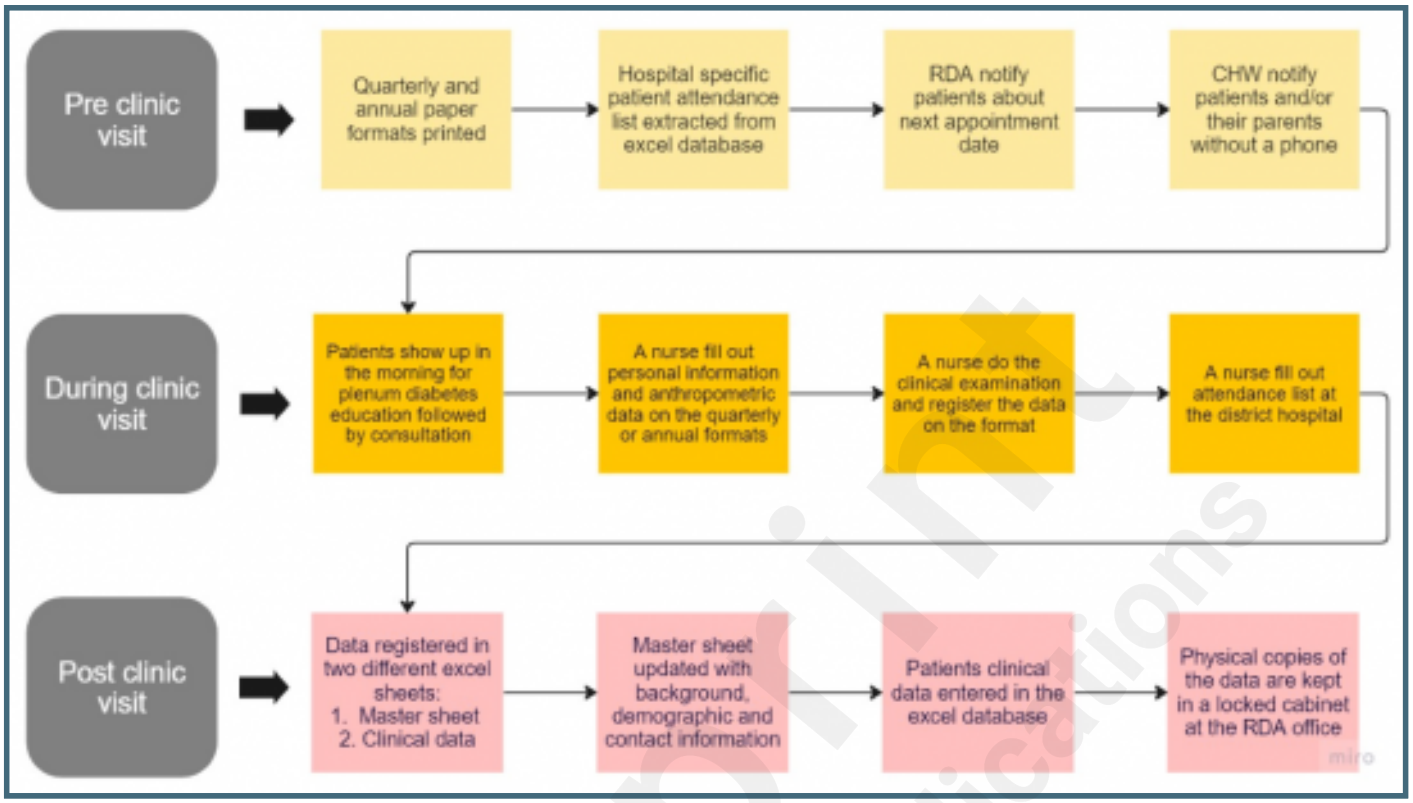
Supplementary Files

Figures

Follow-up and data collection flow.



Theory of change – A set of assumptions about the relationship between themes, project activities and expected short and long-term outcomes.